PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

RECEIVED
OPPT CBIC
04NOV-5 PM 1:10

November 4, 2004

Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for the chemical Resorcinol

Dear Administrator Leavitt:

The following are comments on the test plan for the chemical Resorcinol (CAS# 108-46-3) for the HPV program, submitted by Huntingdon Life Sciences (HLS) on June 15, 2004 for INDSPEC Chemical Corporation (INDSPEC). These comments are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health and environmental protection organizations have a combined membership of more than ten million Americans.

INDSPEC or a contracting party is apparently conducting a multi-generation reproduction study to meet the SIDS data requirement for reproductive toxicity. This test uses thousands of animals. The test plan implies that this study is already started. However, we are confident that had INDSPEC waited for the comment period to end before it started the test, EPA would have accepted data from the 6 pre-existing developmental studies combined with histopathology data from reproductive organs likely examined as part of several pre-existing repeat dose studies as sufficient to fulfill the reproductive data endpoint. This would have obviated any perceived need for further testing under the HPV program for this chemical. Furthermore, there do exist reproductive data summarized in a TERA peer review from March of 2003; this information is not included in the test plan (http://www.tera.org/peer/RSC/RSCWelcome.htm). TERA concluded in their review that resorcinol is not likely to be a reproductive toxicant. This information further supports a weight-of-evidence approach, rather than the use of "check-the-box" toxicology. We are therefore dismayed to learn that the study is already underway. Such an in-depth study would never be required under the purview of the HPV SIDS program.

It is possible the sponsor is conducting this study for other regulatory purposes. If this is the case, that rationale should be included in the test plan for purposes of transparency. Furthermore, all toxicity information, including that referenced and discussed in the TERA assessment should be included. Thus, we strongly urge the EPA to inform the

sponsor that this multi-generation study is not appropriate nor needed to meet HPV reproductive toxicity endpoints.

Finally, as we have observed in past comments, a contract research organization, in this case HLS, should not be assigned the task of preparing HPV test plans as there is, in our opinion, a conflict of interest in having a testing facility to determine whether or not additional testing should be conducted in the HPV program.

Thank you for your attention to these issues. We look forward to a prompt and favorable response to our concerns. We can be reached at 202-686-2210 ext. 335 or via email at *kstoick@pcrm.org*.

Sincerely,

Kristie Stoick, MPH
Research Analyst

Chad B. Sandusky, PhD
Director of Research